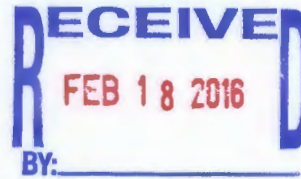


February 18, 2016

VIA Courier and U.S. Mail

National Freedom of Information Officer  
U.S. Environmental Protection Agency  
FOIA and Privacy Branch (2822T)  
1301 Constitution Avenue, NW  
Room 6416 West  
Washington, DC 20004  
Phone: (202) 566-1667

**Donald C. McLean**

Partner

202.857.6469 DIRECT

202.857.6395 FAX

donald.mclean@arentfox.com

**Re: Request for Information Pursuant to the Freedom of Information Act**

Dear Sir or Madam:

On behalf of our client, Dow AgroSciences LLC ("DAS"), we submit this request pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et seq.* This request seeks any and all raw data underlying any federally funded epidemiologic research studies referenced in the U.S. Environmental Protection Agency's ("EPA's") *Literature Review on Neurodevelopment Effects & FQPA Safety Factor Determination for the Organophosphate Pesticides* (Sept. 15, 2015) (the "Literature Review"), which studies EPA reviewed and/or relied upon to support its use of the 10X Safety Factor pursuant to the Food Quality Protection Act of 1996 ("FQPA") in EPA's Chlorpyrifos-Methyl: Human Health Draft Risk Assessment for Registration Review, EPA-HQ-OPP-2010-0119-0020.

For each of the studies identified in the Literature Review,<sup>1</sup> this request seeks the documents or other sources of information (*e.g.*, electronic files) containing one or more of the data elements set forth in the attached Appendix A. Please provide us with copies of the documents and the electronic files containing the raw data.

EPA is relying on the epidemiologic studies in question to "develop[] an agency action that has the force and effect of law," *i.e.*, retention of the 10X FQPA Safety Factor. Accordingly, we request that, pursuant to OMB Revised Circular A-110, EPA request from the studies' authors and release under FOIA any and all data underlying these studies to the extent EPA does not already have the requested raw data in its possession.

This request does not apply to any documents or portions thereof contained in these files that are Confidential Business Information. In addition, this FOIA request does not seek test data, manufacturing processes, or the confidential statement of formula for any pesticide product. Finally, this request does not seek any personnel, medical, or similar files subject to protection under FOIA Exemption 6, 5 U.S.C. § 552(b)(6) (2000). Please note that we are willing to accept

<sup>1</sup> A list of published articles reporting results of the studies is set forth in Table 2.2.5-1, Table 2.2.5-2 and Appendix 3 of the Literature Review. This request expressly excludes raw data DAS has requested in a pending FOIA request submitted to EPA on December 14, 2015 (EPA-HQ-2016-002089).

**Arent Fox**

the requested raw data with personal identifying information redacted or deleted, as necessary to protect the privacy interest of study participants.

We would be pleased to pay reasonable costs related to duplicating and shipping the requested information. Please contact me should it appear that the costs will exceed \$100.

If we may be of assistance with this matter, please do not hesitate to contact me at (202) 857-6469. Thank you in advance for your assistance.

Sincerely,

A handwritten signature in blue ink that reads "Donald C. McLean". The signature is written in a cursive, slightly stylized font.

Donald C. McLean, Esq.

# Arent Fox

## APPENDIX A: DATA ELEMENTS REQUESTED

### INFANT CHARACTERISTICS

Birth weight (g)  
 Head circumference (cm)  
 Birth length (cm)  
 Birth year  
 Gestational age of newborn (wks)  
 Newborn gender/infant sex  
 Infant malformations  
 Apgar scores  
 Sex  
 PON1 genotype

### MATERNAL CHARACTERISTICS

Alcohol use during pregnancy  
 Breastfeeding  
 Cesarean delivery (0 = no; 1 = yes)  
 Community (e.g., Harlem, WH, S Bronx, etc.)  
 Complications of preg and delivery  
 Country of birth  
 Depressive symptoms (CES-D) @ 12 mo  
 Ethnicity (0 = Dominican; 1 = African American)  
 ETS in the home (0 = no; 1 = yes)  
 HOME score (at testing)  
 Household income, annual  
 Illicit drug use during pregnancy  
 Language spoken in home  
 Marital status  
 Maternal age (yrs)  
 Maternal education  
 Maternal hardship  
 Maternal height  
 Maternal IQ  
 Maternal pre-pregnancy weight  
 Maternal smoking during preg  
 Maternal weight gain during pregnancy (lbs)  
 Medications/drugs used during preg  
 Parity (0 = nulliparous, 1 = at least one prior live birth)  
 Poverty level  
 PON1 genotype  
 Race/ethnicity (White, AA, Hispanic, Other)  
 Residential pesticide use  
 Season of delivery (summer, winter, spring, fall)  
 Smoking history, during pregnancy



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EXPOSURE FACTOR	Medium	Source
Cholinesterase at delivery	blood	Mother
Cholinesterase during pregnancy	blood	Mother
Cholinesterase	cord blood	Child
Butyrylcholinesterase	cord blood	Child
Butyrylcholinesterase at delivery	blood	Mother
Butyrylcholinesterase during pregnancy	blood	Mother
Chlorpyrifos at delivery	blood	Mother
Chlorpyrifos at delivery	cord blood	child
TCPy, prenatal sample 1	urine	Mother
TCPy, prenatal sample 2	urine	Mother
TCPy, prenatal sample 3	urine	Mother
TCPy, prenatal sample 4	urine	Mother
TCPy, postpartum	urine	Mother
Chlorpyrifos, week 32-34	air	Indoor
Chlorpyrifos, week 34-36	air	Indoor
Chlorpyrifos, week 36-38	air	Indoor
Chlorpyrifos, week 38-40	air	Indoor
Chlorpyrifos, postpartum	Meconium	Mother
DAP, DEP DAP, prenatal sample 1	urine	Mother
DAP, DEP DAP, prenatal sample 2	urine	Mother
TCPy, Prenatal sample 2	urine	Mother
TCPy, prenatal sample 3	urine	Mother
TCPy, prenatal sample 4	urine	Mother
TCPy, postpartum	urine	Mother
Delivery date/time		Mother Admission date/time
Dates/time of all collection (in context of delivery)		

## CHILD HEALTH ENDPOINTS

BNBAS assessment	<= 3 days; within 5 days; <= 2 months
Baley Scales of Infant Development	6, 12 ,24, 36 months
WISC-IV intelligence test	7 years
WPPSI-III	6 years
CBCL	24 months, 3.5 years
K-CPT	5 years
ADHD	3, 3.5, 5 years
Hillside Behavioral rating scale	
NEPSY	3.5 years
PDD	3, 3.5, 5 years